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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,166	11/12/2003	Lorin Olson	LFS-5001USA-CIP	7031

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EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	PAPER NUMBER
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,166	OLSON ET AL.	
	Examiner	Art Unit	
	Katherine M. Dowe	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/9/2006, 7/6/2004, and 11/12/2003.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-9, 15-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Moerman (US 6,706,049). Regarding claims 1-3, 20, 22, and 35, Moerman discloses a cap (Fig 1, element 10) for a dermal tissue lancing device including a housing (12) and a lancet (30) that is movable with respect to the housing (col 4, lines 15-19). The cap comprises a proximal end (32) for engaging with the housing (element 20; col 4, lines 49-52), a distal end (34) defined by deformable first and second portions (Fig 3A, elements 24 and 26) for engaging with dermal tissue, and an opening (18) defined by an edge of the first and second portions for a portion of the lancet to pass through (col 4, lines 46-48). When the cap contacts and is urged towards the dermal tissue, the first and second portions deform resiliently to reduce the size of the opening, engage the tissue, and approach theretogether to form a bulge in the tissue (Fig 4B; col 7, lines 5-16).

Regarding claims 4-5, Moerman discloses the first and second portions define a continuous circular ring for engaging and surrounding the tissue (Fig 3A).

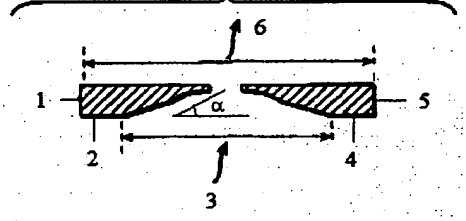
Regarding claims 6-7, Moerman discloses the cap is at least partially formed of a resilient, deformable material (col 10, lines 52-55), including elastomeric materials, polymeric materials, polyurethane materials, or latex materials (col 10, line 56).

Regarding claims 8-9, Moerman discloses the cap is made of a material sufficiently transparent to distinguish a fluid sample to be withdrawn with the dermal tissue lancing device (col 4, line 62 - col 5, line 4). Alternatively, the cap may be formed of a non-blood colored material, such as white (col 5, lines 54-61).

Regarding claims 15-16, Moerman discloses the first and second portions are inwardly bendable (Fig 15), where the inwardly bendable portions contain skin-gripping teeth (col 11, lines 8-11).

Regarding claims 17-18, Moerman discloses the first and second portions have a six-sided cross-section as shown below in Figure 4C. Furthermore, the cross-section includes an internal angle that determines a compressed position of the cap during use, as represented by α below.

FIG. 4C



Regarding claim 19, Moerman discloses the cap is capable of being stackable with other identical caps, since the cap is preferably removably and replaceably connected to the housing (col 12, lines 5-6).

Regarding claim 21, Moerman discloses the cap is capable of applying a pre-lance pressure to maintain the bulge prior to lancing by the device and of applying a post-lance pressure to further maintain the bulge after lancing by the device (col 7, lines 5-16).

Regarding claims 23, 32, and 36, Moerman discloses the cap further comprises a cap body (Fig 7, element 14) and a retainer (60). The cap body has a proximal end (66) for engaging with the retainer and a distal end (16) for engaging with dermal tissue. The retainer has a proximal end (62) for engaging with the housing and a distal end (68) for engaging with the cap body. The distal end of the cap body includes the resiliently deformable first and second (24 and 26) portions, which reduce the opening of the cap body when engaging dermal tissue.

Regarding claims 24 and 27, Moerman discloses the retainer includes a stop (64A) to prevent the proximal end of the cap body from deforming outwardly in a plane containing the opening and to prevent the cap body from deforming in a direction perpendicular to the plane containing the opening.

Regarding claims 25-26 and 31, Moerman discloses the proximal end of the cap body may freely rest within the retainer or may alternatively be fixedly mounted to the retainer or formed integrally with the (col 7, lines 50-54).

Regarding claims 28-30, Moerman discloses a pitot is formed on the cap body (16) and within the retainer such that when the cap is urged towards the tissue, the cap body pivots to fold in on itself within the retainer to reduce the size of the opening (Fig 15). Furthermore, Moerman discloses a weak region is included on the cap body to allow it to fold in on itself (Fig 15).

Regarding claim 33, Moerman discloses the retainer has an inwardly facing recess (Fig 6) for receiving the cap body and an inwardly protruding rim (Figs 7-8, element 70) to cooperate with the outside surface of the cap body (14).

Regarding claim 34, Moerman discloses the cap body is flexible (col 10, lines 52-55).

Regarding claims 37-39, Moerman further discloses the cap for a dermal tissue lancing device may also be coupled with a metering device to extract a fluid sample and measure an analyte within the sample (col 4, lines 40-42). Additionally, Moerman discloses a fluid collection device, such as a test strip, may be placed adjacent the lancing position after lancing to collect and measure the fluid sample (col 1, lines 36-37).

Regarding claims 40-46, Moerman further discloses a method for collecting a fluid sample using the device as previously described. The method comprises contacting the cap with the dermal tissue such that at least the first and second portions engage the dermal tissue, urging the cap towards the dermal tissue such that at least the first and second portions deform resiliently and approach theretogether to close the opening and create a bulge in the tissue, applying a pre-lance pressure to maintain the bulge, lancing the bulge to

create a puncture, applying a post-lance pressure for about five seconds, and collecting a fluid sample, such as a blood sample, from the puncture (col 7, lines 1-16; col 10, line 34 - col 11, line 2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman (US 6,706,049), as applied to claim 1 above, in view of Cunningham et al. (US 6,206,841). Moerman discloses the invention substantially as claimed including a dermal tissue lancing device comprising a housing, a lancet, and a deformable cap. However, Moerman does not disclose the cap is of a graded resilience such that the distal end is more resilient than the proximal end. Cunningham et al. disclose a similar tissue lancing device (Fig 2) comprising a cap with graded resilience. Cunningham discloses the proximal end (Figs 11A-11B, elements 1102 and 1114) should be sufficiently rigid to support the device, while the distal end (1108 and 1110) should be more flexible and of minimal rigidity to contact the tissue (col 18, lines 34-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moerman such that the deformable cap had a graded

resilience. Thus, the proximal end would be more rigid to connect to the housing and offer support for the device and the distal end would be more flexible to conform and contact the dermal tissue.

5. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman (US 6,706,049), as applied to claim 1 above, in view of Patil (US 6,238,575). Moerman discloses the invention substantially as claimed including a dermal tissue lancing device comprising a housing, a lancet, and a deformable cap. However, Moerman does not disclose the device comprises antimicrobial material. Patil discloses a fluid system device comprising a non-leaching antimicrobial agent that inhibits the growth of microorganisms incorporated into the device, such as 2,4,4-trichloro-2-hydroxy-diphenol (col 3, lines 25-28 and col 4, lines 1-2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moerman such that the cap is at least partially formed of an antimicrobial material or such that the cap contains an antimicrobial coating, wherein the antimicrobial material may be a trichlorophenol compound such as = 2,4,4-trichloro-2-hydroxy-diphenol. Thus, when the device comes into contact with body fluids, the growth of microorganisms will be inhibited, allowing the device to be sanitary and safe with a decreased possibility of contaminating the patient with bacteria.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Schmelzeisen-Redeker et al. (US 6,589,260) and Perez et al. (US 2002/0188223).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
January 16, 2007

MJ Hayes

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER